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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/365,576	08/02/1999	DAVID MOORE	00786/246002	1944

21559 7590 08/11/2005

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<i>Advisory Action Before the Filing of an Appeal Brief</i>	Application No. 09/365,576	Applicant(s) MOORE ET AL.	
	Examiner Michael Pak	Art Unit 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 08 April 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 7, 10, 13-16 and 27-31.
 Claim(s) withdrawn from consideration: _____.

Michael D. Pak
 MICHAEL PAK
 PRIMARY EXAMINER

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: The reason for the rejection has been set forth in the previous office actions. With regard to 35 USC 101 rejection applicants argue that the orphan receptors have credible utility. However, the 35 USC 101 rejection is made with regard to the lack of substantial utility because an orphan receptor whose ligand is not known would require further experimentation to determine the function of the receptor. Applicants argue that RIP15 can be administered to inhibit hyperthyroidism because RIP15 would inhibit RXR interaction with thyroid hormone. However, if this was true then all RXR interacting protein such as vitamin D receptor can be used to treat hyperthyroidism and such treatment is not known to one skilled in the art although vitamin D receptor interaction with RXR has been known. Furthermore, no such treatment has been demonstrated with RIP15 and is proposed as a hypothetical treatment. Further experimentation is required and is not in readily available form because for example RIP15 is a nuclear receptor type protein and is found in the nucleus of the cell and the mere administration intravenously will not result in the inhibition of the RXR if it occurs at all in situ. Applicants argue that antibody against RIP15 can be used to detect RIP15 associated disease. However, the specification does not teach the link between the amount of RIP15 and any specific diseases. Thus, the detection of the RIP15 level is not necessarily predictive of a disease state. Furthermore, substantial experimentation is required because the detection with antibodies is not available in a readily usable format where the nexus between RIP15 levels and disease state must be correlated. For example with regard to hyperthyroidism, the correlation is between thyroid hormone and the disease and the nexus to RXR level to disease has not been established much less the RIP15 interaction with RXR and thyroid hormone and hyperthyroidism. Thus, substantial experimentation is required use the antibody in detection of diseases. Applicants argue that RIP15 can be used to isolate B-RARE DNA promoter. However, the isolation does not have specific substantial utility because generally one skilled in the art isolate B-RARE by purification of already available bacterial host cell comprising the B-RARE in a vector and not by RIP15 binding isolation. Furthermore, there is no substantial utility because a nexus between the orphan receptor RIP15 and the use

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